

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
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<http://www.regulations.gov>

**Re: FDA's Voluntary Qualified Importer Program; Guidance for Industry; Draft Guidance. Docket No. FDA-2011-N-0144**

The United Fresh Produce Association ("United Fresh") appreciates the opportunity to comment on FDA's Voluntary Qualified Importer Program ("VQIP") Draft Guidance for Industry ("Guidance").

United Fresh represents more than 1,200 companies at the forefront of the fresh and fresh-cut produce industry, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. United Fresh works to increase consumption of fresh produce for public health, shape legislative and regulatory policies that serve the public and provide for a sound business climate for its members, provide scientific and technical leadership in food safety, quality assurance, nutrition and health, and develop educational programs and business opportunities to assist member companies in growing successful businesses.

### **General Comments**

The following comments were prepared by a working group of thirty United Fresh members who reviewed the draft Guidance line by line. These comments were also informed by a July 20 web conference with FDA officials, who clarified FDA's intentions in parts of the Guidance; these parts may warrant further clarification in the final Guidance.

Much of this Guidance is based on rules that are not yet final. While comments to guidance can be submitted at any time, we request FDA make official opportunities available to comment on this Guidance when applicable rules are made final; e.g., Foreign Supplier Verification Programs (FSVP), Accredited Third Party Certification (A3PC) and Intentional Adulteration.

### **Specific Comments**

#### Eligibility

*C.1, "4. No food you import, including a food you do not intend to include under VQIP, is subject to an import alert or Class 1 recall".*

Particularly in the fresh produce industry, Class I recalls can occur at no fault of the VQIP importer or any of the non-applicant entities; e.g., single detection of *Listeria monocytogenes* on a raw agricultural commodity without evidence of poor practice during follow-up inspection. Involvement in a Class I recall may be an appropriate consideration, if FDA has reason to believe that the contamination was due to negligence, but should not be automatic.

*C.1, "5. Neither you nor the non-applicant entities associated with a VQIP food are subject to an ongoing FDA administrative or judicial action (e.g., Import Alert..."*

Similar to above, Import Alerts can be issued at no fault of the VQIP importer or any of the non-applicant entities. It would be punitive for, for example, a grape importer to lose eligibility because they work with a non-applicant entity that is under Import Alert for cilantro. It would be punitive to the entity under Import Alert if such loss of eligibility for the program causes them to lose VQIP customers for other commodities while they take corrective action on the implicated commodity. This may be an appropriate consideration, but should not be automatic.

*C.1, "6...If you are not the FSVP or HACCP importer for a VQIP food, you ... ensure that the FSVP or HACCP importer is in compliance with the applicable FSVP or HACCP regulations."*

It is unclear in the Guidance what steps must be taken and are sufficient to "ensure" compliance. In the web conference, FDA indicated that procedures sufficient to comply with the final FSVP rule, when published, will also be sufficient for VQIP. We tentatively support this approach.

*C.1, "7. You have a current facility certification for each foreign supplier of food you intend to import under VQIP."*

It is unclear in the Guidance whether a foreign supplier will be eligible for certification if they were subject to FDA action (e.g., detention) in the past and have since taken corrective action. In the web conference, FDA indicated that such an operation would not be ineligible for certification under the A3PC rule if past actions had been appropriately corrected. We support this conclusion.

#### *Foreign Supplier Facility Certification*

*D.1, "The foreign supplier's facility must have a facility certification, which would be issued following a regulatory audit conducted by a third-party auditor/certification body accredited under FDA's third-party accreditation regulations (accredited auditor/certification body), when finalized."*

It is unclear in the Guidance whether a recent FDA inspection of the foreign supplier, or inspection by an FDA-recognized foreign government, would suffice for this requirement. In the web conference, FDA indicated that only a facility certification issued by an accredited third party would be acceptable. We suggest that this restriction could be limiting, particularly in regions where accredited third parties may not be readily available, and unnecessary if FDA or an FDA-recognized foreign government has recently inspected the facility and deemed them compliant with the applicable regulations.

*D.2, "All food manufactured or processed at the facility or grown on a farm for which a facility certification is issued are within the scope of the facility certification"*

It is unclear in the Guidance whether a facility's certification would still be valid if the facility/farm begins to handle a new product. In the web conference, FDA indicated that the facility's certification will continue to be valid, as the certification is specific to the facility. However, that product will not be part of VQIP. We suggest that this be clarified in the Guidance, particularly in regards to limitations to Application Amendments (see I.2 comment, below).

*D.7, "You should coordinate with your foreign supplier to ensure a third-party regulatory audit is conducted and a current facility certification is issued before the expiration of the certification you provided in your VQIP application... FDA will initiate revocation of your participation in VQIP if you import under VQIP a food that is not covered by a current facility certification."*

We suggest that VQIP should allow a suitable grace period if the foreign supplier is in the process of being re-certified, e.g., they have undergone a regulatory audit but the new certification has not yet been issued, or a lack of accredited auditors has delayed scheduling the regulatory audit.

#### VQIP Application

*E.2, "You will also need to attach ... a product label for each food for which you are applying for VQIP participation."*

It is unclear in the Guidance whether this refers to the consumer label or trade label. In the web conference, FDA indicated that, if they are different, the applicant should attach both to avoid misunderstanding. They further indicated that, if there are no product labels, e.g., bulk raw agricultural commodity, then no labels need to be submitted. They also indicated that, if the foreign supplier has different labels for the same product and different labels may be used on imports during the year, all such labels should be attached to the application. We suggest that this be clarified in the Guidance.

#### VQIP Quality Assurance Program (QAP)

*F.2, V. Food Defense Policies and Procedures, "Provide a written description of your food defense system. You should provide your procedures for ensuring your foreign supplier's food defense system is in compliance with FDA's Focused Mitigation Strategies to Protect Food Against Intentional Adulteration regulations (intentional adulteration regulations), when finalized (proposed 21 CFR part 121). In addition, you should provide your procedures for controlling the safety and security of each VQIP food throughout the transportation supply chain."*

It is unclear in the Guidance whether this is applicable if you and your foreign supplier are exempt from the Intentional Adulteration regulation. In the web conference, FDA indicated that operations exempt from the final Intentional Adulteration rule, when published, would also be exempt from this requirement. They also indicated that, if applicable, the level of detail of the food defense system that must be submitted in the QAP would be consistent with the level of detail required in the final Intentional Adulteration rule, and that such information would be considered confidential and proprietary, and so would be redacted, in the event of a Freedom of Information (FOI) request. We tentatively support these conclusions.

#### FDA VQIP Application Review

*H.1, "If you are not in good standing with C-TPAT, we will consider whether factors relating to your C-TPAT participation status affect your eligibility for VQIP."*

It is unclear in the Guidance whether a VQIP applicant's eligibility for VQIP would be affected if they have dropped participation in C-TPAT, or was dropped and did not reapply. In the web conference, FDA indicated that information about the application could be shared

with other regulatory agencies, and such may reveal concerns affects an applicant's eligibility, but that non-participation in C-TPAT alone would not affect an applicant's eligibility. We support this conclusion.

*H.2, "...we will disapprove your application and inform you of the reasons for the disapproval."*

It is unclear in the Guidance whether, if disapproved, that would be communicated to other Federal agencies (e.g., APHIS) or would affect the applicant's import license. It is also unclear in the Guidance whether, if disapproved, the user fee is still payable or, if already paid, refundable. On the web conference, FDA indicated that disapproval of an application would not necessarily be shared with other agencies, unless FDA uncovered issues relevant to such agencies. After the web conference, FDA clarified that the user fee is only payable upon approval of an application, so would not be payable if disapproved. We support these conclusions.

*H.4&5, "FDA ordinarily will conduct a VQIP inspection after your application is approved and prior to October 1 of the first year that you participate in VQIP... FDA will conduct a VQIP inspection to verify that you meet the VQIP eligibility requirements and have fully implemented the food safety and food defense systems established in your QAP."*

It is unclear in the Guidance whether the inspection will be limited to written procedures and records demonstrating compliance with VQIP. In the web conference, FDA indicated that such is their intent. It is unclear in the Guidance whether, if the VQIP inspection is delayed beyond October 1, at no fault of the applicant, and ultimately delayed too long, is the fee still payable and, if paid, refundable? After the web conference, FDA clarified that the user fee is only payable upon acceptance of the application and is required before October 1. Benefits would be granted as of October 1 and FDA would conduct the inspection when they can. No refunds would be given after October 1, when the firm receives benefits. We support that benefits would be granted despite any delay not the fault of the applicant, however we remain concerned that, should the applicant be disapproved as a result of the inspection, the fee would not be refunded. As currently proposed, if the inspection had occurred prior to the fee being paid, and the applicant was disapproved, then no fee would be paid.

#### VQIP Application Amendments

*I.2, "You also may replace the foreign supplier or FSVP or HACCP importer for a food that is already listed in your VQIP application."*

While it is clear that a foreign supplier can be replaced, it is unclear in the Guidance whether another supplier of a VQIP food can be added mid-year by amendment. In the web conference, FDA indicated that a new foreign supplier can be added for a food that is already listed in the approved application. We support this conclusion.

#### VQIP User Fees

*J.4, "On or before August 1 each year, FDA will publish a Federal Register notice announcing the VQIP user fee schedule for the next VQIP year."*

It is unclear in the Guidance whether FDA intends for the user fee to be fixed (i.e., one fee for all applicants) or scaled (e.g., by size of applicant operation or value of previous year's imports of applicant foods).

Revocation of VQIP Participation

*K.2, "The Notice of Immediate Revocation will identify FDA's reason for immediately revoking your participation in VQIP. If you believe revocation was in error, you may contact FDA upon receipt of the notice... FDA will not reinstate your participation in VQIP for the remainder of the VQIP year."*

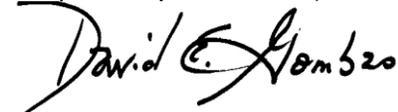
It is unclear in the Guidance whether, if FDA agrees that revocation was in error, participation be reinstated for that year. In the web conference, FDA indicated that reinstatement would occur. We support this conclusion.

*K.5, "FDA will share VQIP revocation information with other Federal agencies, when appropriate, in accordance with applicable statutes and regulations."*

It is unclear in the Guidance when FDA would consider sharing revocation information "appropriate". In the web conference, FDA provided a few examples, but we suggest that these and others be included in the Guidance.

The members of United Fresh hope that FDA finds value in these considered comments.

Respectfully submitted,



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